

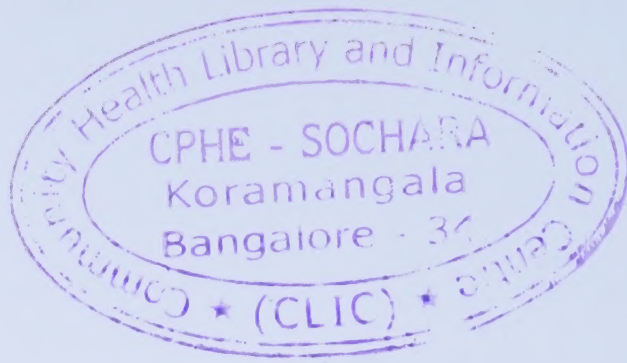
Towards the National Health Assembly III

# ACCESS TO MEDICINES



**National Coordination Committee,  
Jan Swasthya Abhiyaan**

16642



Towards National Health Assembly III  
Booklet 5

## Access to Medicines



National Coordination Committee,  
Jan Swasthya Abhiyan

## **Access to Medicines**

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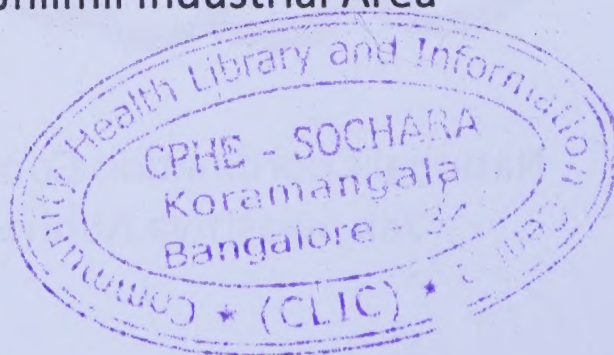
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## About Jan Swasthya Abhiyan

The Jan Swasthya Abhiyan (JSA) was formed in 2001, with the coming together of 18 national networks that had organised activities across the country in 2000, in the lead up to the First Global Peoples Health Assembly, in Dhaka, in December 2000. The JSA **forms the Indian regional circle of the global People's Health Movement (PHM)**. At present it is the major national platform that co-ordinates activities and actions on health and health care across the country. The JSA, today, is constituted of by 21 national networks and organisations and state level JSA platforms (which are present in almost all states in the country). Network partners of the JSA include a range of organisations, including NGOs working in the area of health, feminist organisations, peoples science organisations, service delivery networks and trade unions.

### Perspective and Objectives

The Jan Swasthya Abhiyan believes that despite medical advances and increasing average life expectancy, there is disturbing evidence of rising disparities in health status among people in India and worldwide. Enduring poverty with all its facets and in addition, resurgence of communicable diseases including the HIV/AIDS epidemic, and weakening of public health systems is leading to reversal of previous health gains. The major objectives of the Jan Swasthya Abhiyan include:

1. Draw public attention to the adverse impact of the policies of iniquitous globalization on the health of Indian people
2. Locate the campaign to achieve 'Health For All' in the campaign to establish the Right to Health and Health Care as basic human rights.
3. Need to confront commercialization of health care, while establishing minimum standards and rational treatment guidelines for health care.
4. The urgent need to promote decentralization of health care and build up integrated, comprehensive and participatory approaches to health care
5. Network with all those interested in promoting peoples' health.

## **National Co-ordination Committee Members**

All India Drug Action Network (AIDAN)  
All India People's Science Network (AIPSN)  
All India Democratic Women's Association (AIDWA)  
Bharat Gyan Vigyan Samiti (BGVS)  
Breast Feeding Promotion Network in India (BPNI)  
Catholic Health Association of India (CHAI)  
Centre for Community Health and Social Medicine, JNU  
Christian Medical Association of India (CMAI)  
Forum for Creche and Child Care Services (FORCES)  
Federation of Medical Representative  
Associations of India (FMRAI)  
Health Watch  
Jan Swasthya Sahyog (JSS)  
Joint Women's Programme (JWP)  
Medico Friends Circle (MFC)  
National Alliance of People's Movements (NAPM)  
National Federation of Indian Women (NFIW)  
National Association of Women's Orgs. (NAWO)  
Public Health Resource Network (PHRN)  
SAMA – Resource Group on Women's Health  
SATHI – CEHAT  
Society for Community Health Awareness  
Research and Action [SOCHARA]

### ***Participating Organisations:***

Over 1000 organizations concerned with health care and health policy from both within and outside the above networks.

Website: [www.phmindia.org](http://www.phmindia.org)

# Access to Medicines

## Access to Medicines and India's Health system

One of the pillars of universal healthcare is **access to medicines for all**. The ultimate demand of every health activist has always been the supply of medicines, free of cost, in the public sector; however the population utilising the public sector health facilities is low. Hence, as an intermediate solution, there is a pressing need to work on making medicines more effective, more accessible and less expensive.

### *Is the cost of medicines really a burden on patients?*

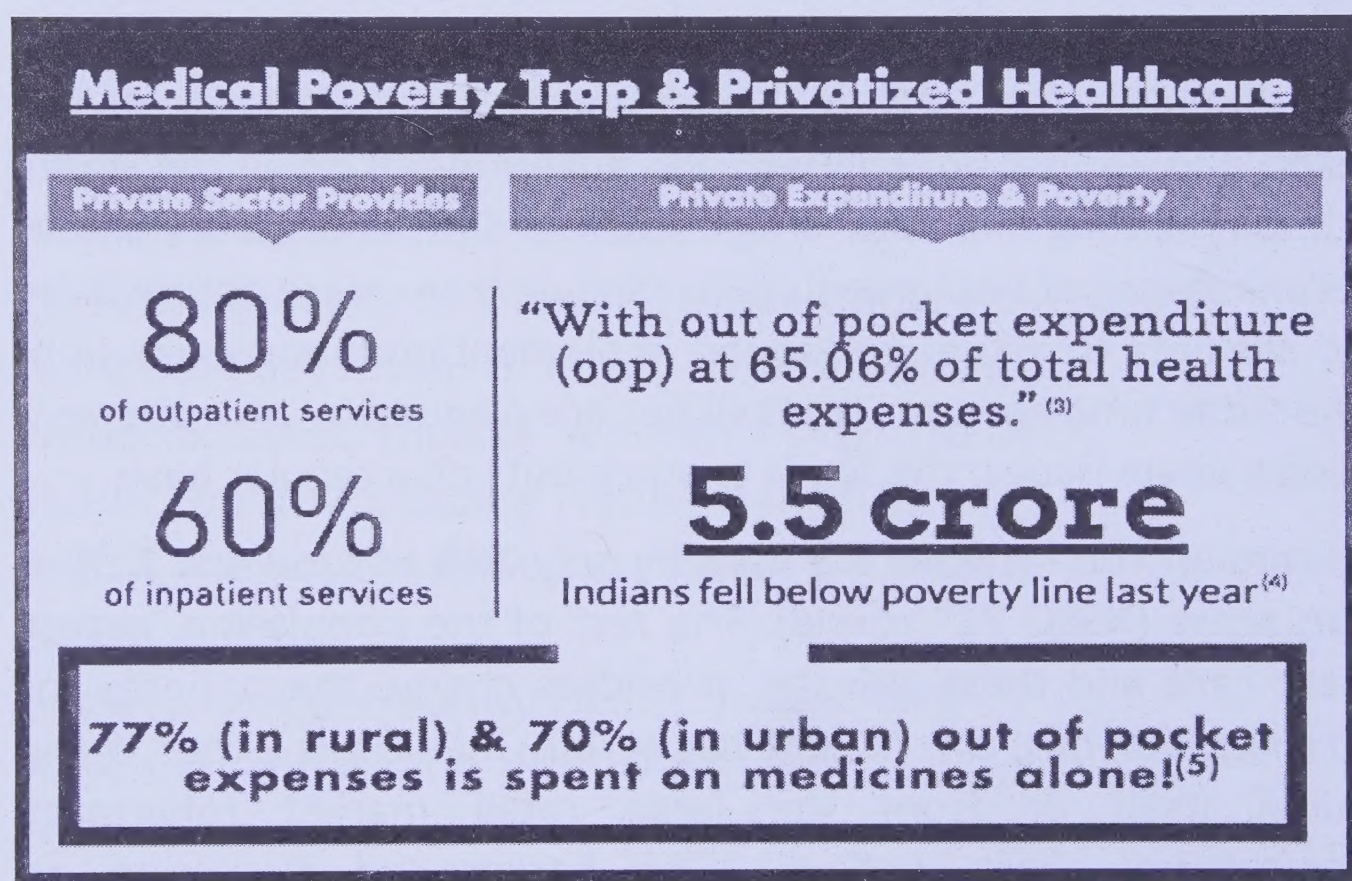
Yes, cost of medicines is the major component of the overall expenditure on health by people. Medicines in public sector are mostly supplied free of cost. Under the aegis of National Health Mission, the Central government and governments of all the states are implementing the free drugs scheme. Different states are at different stages of implementation, ranging from mere approval by state cabinets to actual on ground implementation and execution. At the same time government facilities are plagued by procurement & supply chain issues; this leads to stock-outs on a regular basis.

Government run facilities are used by only 28% in rural and 21% in urban areas (NSSO 71<sup>st</sup> round). The rest of the population, access private care and these private providers charge the patients for medicines. For this, the patient has to buy medicines either in the hospital itself or from the large retail market (pharmacy shops/medical shops/medicos). The background discussion on Access to Medicines in India needs to be understood in the context of the two contrasting trends: 1. India's health system, and 2. India's indigenous pharmaceutical industry.

## India's Health system

India has one of most poorly resourced and managed public health system in India, with public investment on healthcare stagnating at around 1% of GDP since the 1990s. Neoliberal reforms in India, initiated in 1992-93, led to slashing of the public budget for social sectors, including healthcare and led to a virtual dismantling of large parts of the public health infrastructure. Thus, for example, there was a sharp reduction in capital investment in public hospitals between 1991 and 2001. Thus the system is dominated by a largely unregulated private health sector with some unfortunate consequences.

**Figure 1: Highlights of India's private health sector and its consequences**



## India's indigenous pharmaceutical industry

India has the most developed indigenous pharmaceutical industry among Low and Medium Income countries (LMICs) – the third largest in the world by volume of production. The ability of Indian companies to market affordable generic versions of new medicines

at a fraction of the cost charged by Northern pharmaceutical companies has been a major driver of access to medicines in a range of countries, especially for poor patients in LMICs. Ironically, while India has been termed as the 'Pharmacy of the South', the largest numbers of patients without secure access to medicines reside in the country. According to 2004 World Medicines' report by the World Health Organization (WHO), an estimated 649 million people in India did not have regular access to essential medicines.<sup>6</sup> Due to rolling back on elements of regulation in India, such as monitoring and oversight policies, and increasing reliance on market competition, it is now harder to oversee drug policies and to monitor availability and prices.<sup>7</sup> Some indication that the situation in India regarding access remains as dire as earlier reported is available through a comparison of medicine consumption, calculated as number of standard units consumed per 10,000 population. India lies at the bottom of 30 countries surveyed, with reported consumption of around 2 units/10,000 population – lower than Pakistan, Indonesia, Colombia and Jordan.

The benefits of a developed domestic pharmaceutical industry have not translated into universal access to medicines in India because of the poor capacity and outreach of the public health system, which forces patients to directly pay for medicines while accessing healthcare from private facilities. The growth of the domestic industry is also a regulatory challenge given the very large number of manufacturers and products. Poor regulatory oversight has led to the proliferation of a very large number of branded generics – estimated to be between 60,000 to 85,000.

In this rather unique situation, which combines a poorly developed, private sector-led healthcare system and a well-developed pharmaceutical industry, the role of government regulation and the negative effects of regulatory capture by industry have a particularly pernicious impact on public health and peoples livelihoods. Out of pocket expenditure on healthcare amongst the poor – a major portion of which is expenditure on drugs. (Figure 2)

## The threat to Pharmaceutical Manufacturing in India

### *The Success Story of India's Pharmaceutical Industry*

India can take credit for the first major initiative, in a developing country, to attain self-reliance in manufacture of medicines. It is possible to identify three major reasons why this was possible:

- i. **Indian Patents Act of 1970** allowed Indian companies to produce drugs in India that were patented by foreign companies. In a decade the effects were clearly visible and India came to be known as the “**pharmacy of the South**”. Indian companies were able to produce patented medicines, within 2-3 years of their being introduced into the global market, and that too at one-tenth to one-hundredth of the price at which the patented drugs were being marketed. Thus, a huge dent could be made in the **monopoly** enjoyed by European and American pharmaceutical companies.
- ii. **Drug manufacturing by Indian public sector companies:** The Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL) were responsible for starting drug production (from the basic stage, i.e. starting with API manufacture) in India in the late 1950s and early 1960s. It was this pioneering effort by Indian scientists and technologists in these companies that forced foreign companies to also start production in India and paved the way for a slew of private Indian companies to follow suit.
- iii. **Drug Policy of 1978:** The recommendations of the Hathi committee (Parliamentary Committee on Drugs and Pharmaceuticals) were implemented through this policy. This imposed several restrictions on the operations of foreign companies and provided preferential treatment to Indian companies – both in the public sector and in the private sector. The policy also imposed price control on 374 medicines, accounting for over 85% of all medicines in the

market. The result of these measures was dramatic – the share of the Indian market enjoyed by Multinational Corporation fell from over 75% to less than 25% within a span of a decade.

### ***The Reversals in Public Policy and its Impact***

Unfortunately, all these three initiatives have been reversed in the last two decades. HAL and IDPL were systematically undermined as a result of inept management and withdrawal of preferential treatment. The 1978 policy's major thrusts were diluted and reversed in successive policies in 1986, 1994 and 2002. The entire range of protection that was provided to Indian companies, vis-à-vis multinational companies have been withdrawn. Further, the 1970 Patent Act was amended in 2005, because of India's annexation to the World Trade Organisation (WTO) in 1995 which compelled it to sign the Agreement on Trade Related Intellectual Property Rights (TRIPS). As a result, Indian companies do not have the automatic right, any longer, to produce medicines whose patents are held by foreign multinationals.

### ***De-industrialization and Export-led Growth***

The most disturbing trend in the drug industry is the frightening pace of de-industrialization. **Many companies are now dependent on imported Active Pharmaceutical Ingredients (APIs).** Over the years, many large companies have cut down API production and are increasingly acting as mere formulators and traders (i.e. using imported APIs to produce finished formulations). In many therapeutic groups, major production is accounted for by the Small Scale sector and, in many cases, the latter depends heavily on imported APIs- i.e. they function as suppliers of imported APIs to large companies. This tendency has been fueled by liberalization in the Industry, making imports easier. It has also been helped along by the scrapping of 'ratio parameters' which had made it mandatory that a certain percent of a company's turnover be made up of by drug production from the basic stage (i.e. API

manufacture). The shift in interest of large companies, from manufacturing to trading, has also been a consequence of the massive decontrol of drug prices. **Price decontrol** has led to a spiraling rise in the prices of finished products (also called formulations) and has reduced the incentive to produce APIs (where the returns are much lower).

Of additional concern is the dependence on China for API imports. Over half of Indian API imports now come from China. This has serious implications for the survival of the Indian generics industry. It is inconceivable that the Chinese Pharmaceutical industry will continue to remain – for the global market – principally a supplier of APIs. When China does enter the global ‘finished products’ market – which it is starting to do – they will have a clear competitive edge over the Indian generics industry, given China’s stronger base for API manufacture. As we discuss later, a bulk of the growth of India’s generic industry is driven by growth in exports, which would be threatened by competition from China. Another significant shift that has gone virtually unnoticed, but merits close scrutiny is that, a **huge share of the manufactured output of the Indian pharmaceutical sector is exported**. About 63.9% of sales of top 25 Indian companies are accounted for by exports. For eight of these, excess of 80% of sales are accounted for by exports.

Further, a bulk of these exports is now routed to developed country markets. In 2011, of the top 26 destinations of exports accounting for 66.43% of total pharmaceutical exports from India, 23.45% went to the US and a further 20.15% went to other developed country markets (data from [www.pharmabiz.com](http://www.pharmabiz.com)). This has implications regarding the business strategies of Indian generic companies. Their increasing dependence on exports, and especially exports to Europe and North America, puts them in a position where they need to align their policies with interests of countries of the North. This could translate into a much more subdued articulation of national interests, viz. in the form of support for lower standards of IP

protection. Business decisions and policies of major Indian generic companies are likely to be increasingly informed by their necessity to collaborate with big Pharma.

### **Indian Companies as 'Partners' of 'Big-Pharma'**

The post-liberalization effects on Indian industry is now unravelling. Many large Indian private sector companies, having embraced the notion of a strong Patent regime, in the hopes of future tie-ups with MNCs. Domestic companies are increasingly looking for such tie-ups where domestic facilities will be used for outsourcing of both R&D and manufacture. Indian companies seek to leverage upon the advantages of cheap manufacturing and R&D costs to build such linkages with MNCs.

In return they would expect accelerated entry into the large Northern markets. The catch here is, that they would function as "junior partners" and would be subservient to the interests of big Pharma.

"Strategic' tie-ups with 'Big-Pharma' have been accompanied by acquisitions of Indian companies by MNC. Acquisitions have been facilitated by the liberalization of Foreign Direct Investment (FDI) norms for the pharmaceutical sector in 2001. Currently, 100% FDI is allowed through automatic route (without prior permission) in pharmaceutical manufacturing except sectors using recombinant DNA technology. The FDI policy does not make any distinction between 'Greenfield' and 'Brownfield' investments.

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## *Implications for Health Security*

Clearly, there is compelling evidence that we stand to fritter away all the gains of the 1970s and 1980s. The Indian drug industry, built by diligent application of public policy that sought to achieve self-reliance in the pharmaceutical sector, is poised to be handed over to Foreign Multinational corporations. The Government of the day, in pursuit of reforms, appears to be a willing accomplice. The Indian industry is faced with the twin danger of a resurgent Foreign Sector poised to strike, armed with a strong Patent regime, and an Indian Sector that is increasingly dependent on imported APIs. A possible safeguard against such threats -- the Public Sector -- has all but been wound up. The implications for self-reliance and health security are obvious.

## **Cost of Medicines**

Regulation of drug prices and production of drugs by government are needed due to the fact that health is its responsibility. The following factors also form a part of the argument for a state role in manufacturing and regulation of medicines:

- i. The accepted market based discourse is that prices of medicines will be low in a free market economy due to competition. But the limitation in context of medicines is that the consumer does not have a choice as he is advised by the doctor/health professional. **Prices are dominated by few large brand leaders or oligopolistic cartels.**
- ii. Another reason for high costs is the presence of a globally binding product patent system wherein some companies have **monopoly** over a particular drug.
- iii. All private manufacturers are interested in maximising profits and **do not bother about affordability or quality.** In order to deal with this issue it is necessary that the government should produce all essential medicines.

One point of interest that separates India from other nations in the context of purchase of medicines is that a large proportion of transaction happens in retail sales (medical shops/medicos/pharmacists/internet sales etc.) as against institutional sales (hospital). The percentage of medicines sold in the retail is around 70% and the remaining 30% is in the institutions. In the developed world, the exact opposite pattern of sales is seen.

### Cost of medicines

The basic cost of a product is set by the components that are involved in its manufacturing and sale. The following are the main components in the price of a drug :

- i. **Raw material** – the cost of the active ingredient and its content in the final formulation plus the cost of the bulk drug (API) which in turn are dependent on the cost of the raw materials used to manufacture them.
- ii. **Packaging costs** – this component is often manufacturer dependent. Fancy packaging is more expensive than simpler packaging. Similarly, strip packing or blister packaging is more expensive than bulk packaging.
- iii. **Manufacturing cost or Conversion Cost:** These costs include the cost of infrastructure, labor, electricity, water, etc.
- iv. **Quality control** – manufacturing units are required to carry out in house quality control, which contributes to the cost of a drug.
- v. **Yield/loss:** There are losses incurred during manufacturing. The average loss in the case of tablets or capsules is taken as 2% and in the case of syrups is 5%.
- vi. **Post manufacturing expenses:** Under post manufacturing expenses we have the following sections :
  - a. Transportation costs
  - b. Trade margins- given to agents/distributors/retailers
  - c. Promotion costs –marketing/hiring/incentives

- d. Profit margin – to the manufacturer included as post manufacturing expense

vii. Taxes

- a. Goods and Services Tax (GST)
- b. Customs tax ( if the medicine is imported)

## Regulation and Drug Price Control in India

Drug Price Control Order (DPCO) regulates the prices of only a fraction of drugs in the market and those drugs whose prices are controlled are notified in the relevant DPCO. In the case of remaining drugs, the prices are not controlled and companies are at liberty to charge accordingly.

### DPCO regimens over the years

The way drug prices are regulated has changed fundamentally after 2012. Hence we need to look at the history of DPCOs before and after 2012 separately. The history shows how simple policy changes are twisted in favour of the private sector and against the interest of people. Over the years different DPCOs have specified different formulas to regulate the prices of Bulk and Formulations. Different DPCOs also covered different number of drugs.

**Table 1. Regulations and methods over the years**

Year	Regulation type	Method	No. of drugs under price control	Criteria used to be kept under price control	Percent of market covered
1979	Cost Based pricing	Based on the	342	Essential medicines	90%

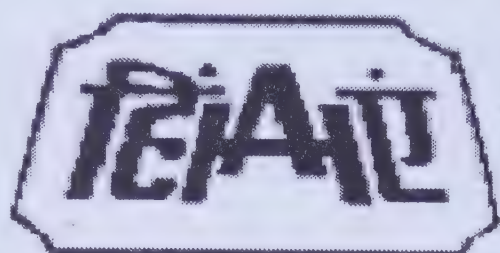
1987	Cost based pricing	costs of manufacturing	142		70%
1995	Cost based pricing		76		50%
2012	Market Based pricing	As an average of the existing	348	Essential medicines	18-20 %

### DPCO regimens before 2012

India was among the first countries in the developing world to formulate a national drug policy and introduce price control on pharmaceuticals. In the 1950s, drug prices in India were among the highest anywhere in the world - a fact commented upon by Kefauver committee (an US Senate committee), which said, "As a matter of fact, in drugs generally India ranks among the highest priced nations in world". In the 1950s, India was fully controlled by Multinational Companies.

In 1954, with the help of WHO and UNICEF, India set up the Hindustan Antibiotics (HAL) and later in the 1961 IDPL ( Indian Drugs and Pharmaceuticals Limited) was set up with the help of Soviet technology. ***With the setting up of the public sector institutions, antibiotic prices fell by as much as 60 to 70%.***

Subsequently the Indian private sector started manufacture on a large scale and was able to substantially improve their capacities in indigenous production of medicines. In spite of all these advances, the MNCs were able to maintain their grip on the market due to their marketing strategies.



**Hindustan  
Antibiotics LTD**

**1954**

**Hindustan  
Antibiotics**



**1961**

**Indian Drugs and  
Pharmaceuticals  
Limited**

### ***DPCO 1979***

In 1974, the governments setup the Committee On Drugs and Pharmaceuticals, popularly known as 'Hathi committee'. The committee's recommendations are seen as a landmark for drug industries in the Third World. It was the basis of the drug policy of 1978 and the Drug Price Control Order (DPCO) 1979 were based on recommendations of the committee. **For the first time, effective price control mechanism was introduced in the country in 1979. The 1978 policy led to rapid growth of the Indian pharmaceutical sector, which soon gained the capability of producing most essential drugs as it proactively promoted the domestic industry – both public, as well as the private sector.**

An associated development which promoted indigenous drug production was that In 1970 India replaced the old pre-Independence 1911 Patents Act and excluded pharmaceutical products from product patents. This allowed the domestic companies to introduce new drugs, which were under patent, into the Indian market within 3-5 years of their introduction in the global market, curbing the monopoly of MNCs.

The government could fix the sale prices of 347 bulk drugs and 4,000 formulations in the country precisely due to DPCO 1979 order. The DPCO covered up to 90% of the market. The order classified medicines into four classes and imposed controls on the first three categories.

**The classes of medicines and control after DPCO 1979**

Life Saving	Essential	Less Essential	Non-essential (simple remedies)
Price controlled	Price controlled	Price controlled	Non controlled
MAPE- 40%	MAPE- 55%	MAPE- 100%	MAPE- Not applicable
90% market covered	90% market covered	90% market covered	10% market covered

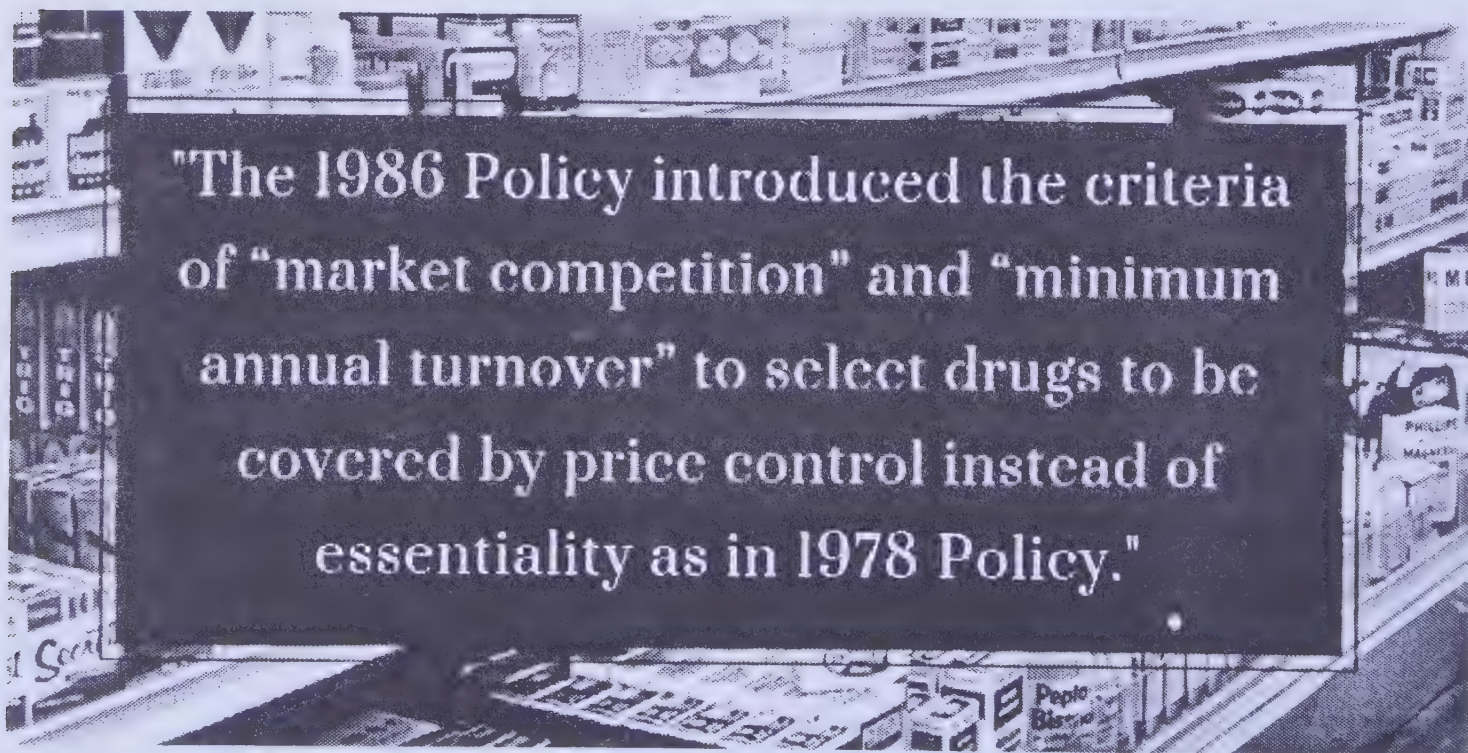
In the order there has been a ceiling to the mark up (MAPE- Maximum Allowable post manufacturing expenses). Additional limits of “leader prices” were also imposed for formulations in category 1 and 2. Leader prices were based on the most popular brand and manufacturers of similar formulations could not exceed these. For category 3 formulations, separate pricing for each product was proposed. The retail prices of scheduled formulations were controlled by using a “COST-PLUS” approach, which meant that the cost of medicine would be Ex-factory costs along with Mark up and taxes.

In 1980s the public sector units such as Hindustan Antibiotics Limited and Indian Drugs and Pharmaceuticals Limited lost ground and went into a downward spiral due to **gradual withdrawal of government support in keeping with the overall policy shift towards a liberal economy.**

The serious flaw in the 1978 policy of not proposing production controls while proposing a differential mark-up led to companies shifting production away from the controlled categories.

### ***DPCO 1987***

The 1986 policy reversed many features of the 1978 Policy due to pressure from both foreign and large Indian drug companies. The result was lesser government control and a shift towards market based pricing criteria for choosing drugs under price control. The span of price control was drastically reduced, more profits were allowed in the form of increase in mark up and also imports were liberalized. The policy can be viewed as a step towards deregulation of the industry in regards to production and price controls.



Also, the number of drugs controlled decreased from 347 to 142. The policy proposed two categories of drugs to be placed under price control, instead of three (see Table).

# Medicines and control after DPCO 1987

Medicines used in National Programs	Other Essential medicines	Non-essential medicines
MAPE- 100%	MAPE- 100%	MAPE- Not applicable
70% market covered	70% market covered	30% market covered

The 1986 policy further reversed other provisions by relaxing sectoral reservations and permitting bulk drug production by companies regulated by FERA except those reserved for manufacture by the public and small-scale sectors. Thus, for example, Penicillin and Polio vaccine which were reserved for manufacture by public sector in the 1978 policy were opened to private sector.

In the 1980s and 1990s some disturbing trends started to emerge:

- a. Companies started competing in production of costly new medicines for lifestyle diseases predominantly affecting those belonging to the upper socio-economic strata.
- b. This led to oversupply of expensive but under supply of less expensive drugs, ignoring actual demands.
- c. To maximize profits, larger companies started exporting a major proportion of indigenously manufactured medicines.

## DPCO 1995

In continuation with the trends of the 1986 policy, the 1994 policy further provided concessions to industry in the form of lesser price and production controls. Drugs under price control were chosen not on public health needs but on market based criteria such as existing competition. The number of drugs reserved for public sector was reduced to five from the existing fifteen, and was completely abolished in 1999. The Hindustan Antibiotics Limited and Indian Drugs and Pharmaceuticals Limited had now become terminally “sick”.The DPCO, 1995 further reduced the number of bulk drugs under price control from 142 under DPCO, 1987 to 74 covering

around 50% of the market. All drugs under price control were now brought under single category with a uniform MAPE of 100%.

The policy, thus, responded to the plea of the private sector that the drug industry should be decontrolled – both with regard to production and pricing. However, the industry's claims that profitability was going down was a false argument as drug companies had consistently shown large increases in profit in their annual reports. The changes in the drug policy were in tandem with the state policies in favour of market forces. Later in the year 1997, the NPPA (National Pharmaceutical Pricing Authority) was formed under the department of Pharmaceuticals to oversee matters related to pricing of medicines.

### The developments since 2003 and its outcome

In 2003, AIDAN (All India Drug Action Network) petitioned the Supreme Court on the increasing burden of medicines on the citizens and its regulation.



In response, the SC directed the government to devise a policy that would ensure essential medicines are available at affordable costs.

So, a group of ministers (GOM) committee recommended in 2012 that all essential medicines should be brought under price control.

*However, instead of using the cost based formula, the GOM suggested a market based price control despite the SC's suggestion.*

*This is largely attributed to the political and financial clout of the private corporations and the neglect towards public health in India.*

## DPCO 2013

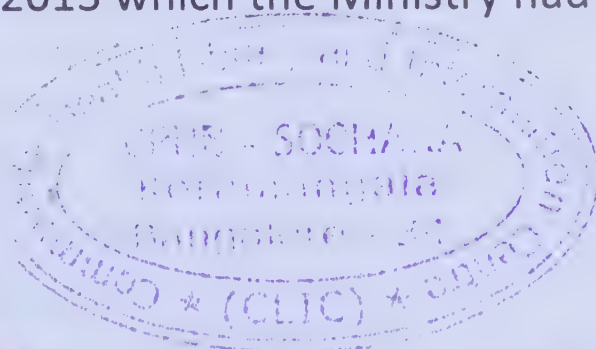
Keeping the interests of the pharmaceutical industry in mind, the DPCO 2013 changed the formula of price control to a “market based” mechanism, calculating the ceiling prices by averaging the cost of all brands owning 1% market share for the same. Essentially, the DPCO 2013 chose a method which allowed the pharmaceutical companies to continue exploiting the price elasticity in healthcare.

Additionally, the control applied only to specific drugs in the specific dosage mentioned in the essential drug list. Also, it applies only to the formulations. This step was the exact opposite of the previous methodology where in all combinations of the drug with any other drug and all its dosage forms and delivery forms (injections/tablets/syrups etc) were under control.

Since, DPCO 2013 is confined to the specified drugs and their dosages indicated in the Essential Drug List, the span of price control is very modest at best. An analysis of two essential drugs – Paracetamol and Glibenclamide – shows that only 20.87 per cent and 35.70 per cent, respectively, of all products containing these two drugs was covered by price control.

Despite claims to the contrary, the Drug (Prices Control) Order, 2013, when announced covered only 1.7 percent value of the total market. DPCO 2013 has cleverly diluted the whole process of price control. It in fact has created numerous escape routes for the private sector to evade price controls.

Following severe adverse criticism the NPPA has expanded the span of control. However no significant relief could be provided as total price benefit remained insignificant. NPPA itself then proposed a large number of amendments to DPCO, 2013 which the Ministry had not yet accepted.



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## World Trade Organization and Patents

Pharmaceuticals are the most important health-related products that are traded, accounting for 55% of all health-related trade. The top 20 transnational corporations, based in the USA, the UK, Germany, Switzerland, and France, each have an average of more than 100 foreign affiliates in more than 40 countries (including 19 developing countries), with average sales of over \$20 billion in 2008-09. However there are some exceptions — countries such as India, Brazil and Thailand, have substantial capacity to produce generic medicines.

The Indian pharmaceutical industry which grew because of the support of the 1970 Patent Act (now amended) and support from the 1978 Drug Policy is called the 'Pharmacy of the South'.

- Indian companies supply affordable medicines to over a hundred countries.
- 92% of patients on antiretrovirals in LMICs use generic drugs<sup>i</sup>, mostly from India (2007- 2008)
- About 50% of the essential medicines that UNICEF distributes in developing countries come from India.<sup>3</sup>
- 75-80% of all medicines distributed by the International Dispensary Association (IDA) are manufactured in India.<sup>3</sup>

An important determinant of India's ability to continue to produce low-cost generic equivalents of patented drugs is the flexibilities available in the Indian Patent Act. The final amendments to India's Patent Act, in order to make it TRIPS compatible, were incorporated in 2005. While the process was extremely contentious, a conjuncture of circumstances led to several health safeguards being included in the Act. The safeguards are not perfect and there have been arguments regarding how they could have been better framed. However, the safeguards do offer avenues for mitigation of the impact of a product patent regime, and the Indian law is now widely seen as an example of how the TRIPS flexibilities can be effectively incorporated in national laws.

## Free Trade Agreements: The New Frontier

While considerable attention has been focused on the World Trade Organization (WTO), and the binding trade rules that it imposes on member countries, there is a shift towards much of trade negotiations being conducted bilaterally and with regional blocks. These Regional and Bilateral Trade Agreements are an increasingly important part of the governance of global trade, and consequently have large impacts on the health sector across the world. From 1990 to 2007, the number of such agreements notified to the GATT or the WTO increased from 20 to 159. At present, over 250 regional and bilateral trade agreements govern more than 30% of world trade.

Of particular importance to discussions regarding access to medicines are the ongoing negotiations in the RCEP and the India-EU FTA. While Indian negotiators appear to have successfully warded off some demands for TRIPS-Plus measures (that is measures requiring stronger IP standards that go beyond the TRIPS agreement) such as data exclusivity, 'patent linkage' and 'patent term extensions', according to leaked texts of the negotiations several areas of concern remain (especially related to 'IP enforcement').

The US continues to exert bilateral pressure on India to provide for higher IP standards. There has been a recent spate of such pressures again, perhaps triggered by several progressive judgments by courts and the patent office in India (eg. the granting of the first CL in India; the Supreme court judgment denying a patent to Novartis; etc.).

## **Recommendations by Jan Swasthya Abhiyan**

The Jan Swasthya Abhiyan demands that the new Pharma Pricing Policy be withdrawn and prices be calculated on the basis of actual manufacturing costs, and not on the rigged prices set by the private Pharma makers. The JSA also demands that the practice of fixing bulk drug prices not be discontinued. We further have some suggestions regarding the country's drug policy:

### ***Independent mechanism of Data Collection:***

In order to be able to track the pharmaceutical market the Government needs to set up its own mechanism of collecting data on the market for medicines.

### ***Monitoring of Entire Therapeutic Category***

When an essential drug is under price control, a continuous monitoring of the therapeutic segment to which the drug belongs to, should also be carried out. It is not enough to bring only one medicine under price control out of the range of medicines in the category to which this medicine belongs. Otherwise Pharma companies would mislead and entice doctors in to prescribing these 'me too' drugs. 'Me too drugs' should have the same price ceiling namely the ceiling of the original drug.

### ***Tax Reduction***

All drugs under Essential Drug List should be exempted from GST and for other drugs only 5% GST can be applicable.

### ***Weed out Irrational Drugs***

To make price controls more effective the Ministry of Health needs to urgently weed out such drugs from the Market. The Government's notification banning 328 Drugs in September 2018 is a step in the right direction but falls far short of the need as companies are constantly developing new irrational combinations.

It is necessary that a comprehensive policy be developed to weed out ALL irrational combination drugs.

***Registration of New Drugs:***

The DGCI must be much more judicious in allowing registration of new drugs, keeping in mind public health benefits and risks.

***Voluntary Price Control of New Drugs:***

Manufacturers of any new drug which is registered should be asked to provide cost data, and even if the drug is not under price control they should be asked to conform to a voluntary regulation where, in no case, is the mark up over costs, more than 150% for a period not exceeding 5 years.

***Price Fixation of Drugs:***

While computing the price to be fixed, the cost of manufacture of generic drugs should be taken into account. In no case should the notified price be more than the average price of generic manufacture.

***Strengthening of NPPA:***

NPPA needs to be strengthened and provided with more regulatory teeth. It is unfortunate that the Niti Ayog seems to want to abolish NPPA to provide a free run to pharma companies.

***Revival of Public Sector Units (PSUs):***

Public Sector Units can play the role of a bulwark against high prices charged by private companies and can also be used to fill in gaps when Private Companies stop production of essential medicines because their prices are controlled. The revival of PSUs in the pharmaceutical sector is an urgent necessity.

***Pooled Purchasing to Minimise Costs in the Public Sector:***

In the past decades some states (especially Tamil Nadu and more recently Rajasthan) have put in place mechanisms like “pooled

purchasing” in order to reduce the costs of drug procurement in the public sector. The experience in using such mechanisms should be studied in order to arrive at a set of recommended practices that all state governments and the central government can follow.

### ***Rational Drug Prescribing and Use***

The Ministry of Health should prepare Standard Treatment Guidelines for common illnesses; and prescriber information and an annual National formulary need to reach every registered practitioner in the country free of cost.

### ***Develop and Introduce a Statutory Code on Marketing Practices***

It is unfortunate that in spite of several rounds of deliberations the government has not mustered the courage to curb the gross unethical marketing practices of pharma companies. The unholy nexus between companies and a section of doctors leads to irrational practices and promotes the sale of expensive and unnecessary medicines.

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# **Jan Swasthya Abhiyan**

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